Patients' right to safe medication: Legal framework relating to private pharmacy practices in Sri Lanka

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The right of patients to safe and quality medication is a fundamental aspect of the right to health recognized under international law. World Health Organization (WHO) emphasizes safe medication practices as a core element of health systems. Pharmacies are part of an integrated medical structure that provides healthcare services. Sri Lanka has an enriched health care system including both public and private sector. The National Medicines Regulatory Authority Act, No. 5 of 2015 is the main piece of legislation that aims to ensure the availability of safe, effective, and affordable medical products in Sri Lanka. It established the National Medicines Regulatory Authority (NMRA) to oversee the regulation, registration, licensing, and control of medicines, medical devices, and borderline products. However, successful implementation of private pharmacy regulations appears to be uncertain. Also, there is no explicit guarantee for the right of patients for safe medication or the right to health under the Sri Lankan constitution. Although, private pharmacies play a vital role in a healthcare system, concerns have emerged about the quality of medicines dispensed, ethical practices, regulatory oversight, protection of patients' rights, counterfeiting, inadequate public awareness and overall patient care in Sri Lanka. This study examines the laws governing medication dispensing by private pharmacies in Sri Lanka, focusing on patients' right to safe medication as an integral part of the right to health under Article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR, 1966). It includes a comparative analysis of international law and Sri Lankan legislation to assess compliance and identify gaps. The study further evaluates key challenges to safe medication, including existing legal frameworks, implementation gaps, the absence of constitutional guarantees, and the role of professional ethics and regulatory oversight. Employing doctrinal research method, the analysis draws on a comprehensive review of primary and secondary sources. Finally, this paper proposes legal and policy reforms aimed at strengthening patient rights, enhancing pharmacy regulation, and improving access to safe medicines with reference to relevant legal and institutional protections in India.

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